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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/338,729 06/23/99 GROSS

D 10853/1

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HM12/0605

EXAMINER

BERMAN, A

ART UNIT

PAPER NUMBER

1619

DATE MAILED:

8

06/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Applicant(s)

09/338,729

Applicant(s)

GROSS, DENNIS

Examiner

Alysia Berman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 27-30, 34 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26, 31-33 and 36-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

1. Receipt is acknowledged of the election filed April 12, 2001. Claims 1-44 are pending.

Election/Restrictions

2. Applicant's election without traverse of lactic acid and a pad in Paper No. 7 is acknowledged.

3. Claims 27-30, 34 and 35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species of the invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5.

4. Claims 1-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and/or species of the invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5 and 7.

5. Applicant's election with traverse of Group II, claims 10-23 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that search and examination of all claims in a single application would not present an undue burden. This is not found persuasive because the composition claims do not require two compositions, one being acidic, or an applicator as required by the method claims and the claims directed to a kit. Therefore, a separate search would have to be conducted for the method and kit claims that is not required for the composition claims.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 10-23, 31-33, 36 and 40-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for hydroxy carboxylic acids, keto acids, hydroxybenzoic acids and trichloroacetic acid, does not reasonably provide enablement for an acid suitable as a skin renewing acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification does not provide an exclusive definition of a skin renewing acid. Additionally, the specification does not provide a definition of "skin renewing." One skilled in the art would not be enabled to determine what other acids would be considered suitable for skin renewing without undue experimentation.

8. Claims 10-26, 31, 33 and 36-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for sodium bicarbonate and sodium hydroxide, does not reasonably provide enablement for an alkaline agent suitable for use in skin care. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification discloses only

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sodium hydroxide and sodium bicarbonate as suitable alkaline agents. Alkaline agents can be irritating and corrosive to the skin. One skilled in the art would not be enabled to determine what other alkaline agents would be suitable for use in the skin care compositions without undue experimentation.

9. Claims 10-26, 31-33, 37, 38, 40, 41, 43 and 44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 0.1-10% of hydroxy carboxylic acids, keto acids, hydroxybenzoic acids or trichloroacetic acid, does not reasonably provide enablement for an effective amount of an acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The amount of acids used in skin care compositions must be limited in order to avoid adverse and dangerous effects. The disclosure is only enabling for an amount of 0.1-5% of hydroxy carboxylic acids, keto acids, hydroxybenzoic acids or trichloroacetic acid. One skilled in the art would not be enabled to determine the safe and effective amount of acid without undue experimentation.

10. Claims 10-26, 31-33 and 36-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 0.1-15% of sodium bicarbonate or sodium hydroxide, does not reasonably provide enablement for any amount of an alkaline agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Alkaline agents can be irritating and corrosive to the skin. In order to avoid these adverse and sometimes dangerous

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effects, the amount of alkaline agent in skin care compositions must be limited. The specification discloses an amount of 0.1-15 wt.% alkaline agent. The specification is not enabling for using any amount of alkaline agent to make a safe skin care composition. One skilled in the art would not be enabled to determine the safe and effective amount of alkaline agent without undue experimentation.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 10-26, 31-33 and 36-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. The claims are indefinite because they recite percent amounts of components in the compositions but do not recite units of measurement. Are the percents by weight or volume?

14. The term "skin renewing" in claims 10-23, 31-33, 36 and 40-44 is a relative term that renders the claims indefinite. The term "skin renewing" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what is encompassed by a "skin renewing" acid.

Response to Arguments

15. Applicant's arguments filed December 21, 2000 have been fully considered but they are not persuasive.

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16. Applicant argues that the specification provides sufficient enablement of skin renewing acids and alkaline agents as disclosed at pages 5-6 and 8-9, respectively. The specification does not provide an exclusive definition of either the skin renewing acids or the alkaline agents that are suitable in the compositions. The term "skin renewing" is not defined in such a way as to determine what is encompassed by a "skin renewing acid." Therefore, one skilled in the art is not enabled for any other acids that may be suitable for skin renewing or any other alkaline agents that may be suitable in the compositions.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 10-21, 23-26, 31, 32, 36, 37, 39, 40 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,720,949 (949).

US '949 discloses a cosmetic mask comprising a first composition and a second composition that are applied sequentially to the face. One of the compositions comprises an acid and the other comprises an effervescent agent (abstract). The effervescent agent is preferably sodium bicarbonate and the acid is an alpha-hydroxy acid such as lactic acid (col. 2, lines 35-38). The compositions may be applied using a spatula or any other convenient applicator (col. 2, lines 42-47).

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The effervescent composition may comprise from about 1-20% of a surfactant system (col. 3, lines 31-33). Surfactants such as cetareths, ceteths, laneths, nonoxynols, octoxynols, glyceryl stearate, PEG-castor oil, poloxamers, poloxamines and steareths are disclosed at column 5, line 47 to column 6, line 35. US '949 discloses ethoxylated sorbitan esters with fatty acids or alcohols and ethoxylated esters having preferably 14-18 carbon atoms, which encompassed polysorbate-20 (col. 5, line 60 to col. 6, line 4).

The pH of the effervescent composition is from above 7.5 to about 9, preferably between 7.8 and 8.3 (col. 7, lines 58-60). The pH of the acid composition is from about 3.5 to about 6 (col. 8, lines 50-64). As a further note, pH is an inherent property of an acid or alkaline agent. Therefore, the pH of a composition comprising an acid or an alkaline agent is inherently either acid or basic, respectively, unless specifically altered.

For additional suitable acids, see column 9, lines 8-13. See Example 1 at column 12 for one composition comprising 5.0 wt.% sodium bicarbonate, 1.5% glyceryl stearate, 5.0% cetyl alcohol, 1.5% PEG-100 stearate and 1.5% PEG-40 castor oil with a pH of 8.0 and another composition comprising 9.1% lactic acid with a pH of 4.9. The reference teaches at column 13, lines 7-9, that the composition bubbles because of the reaction between the effervescent agent and the acid. This is interpreted as meaning that the alkaline, effervescent agent neutralizes the acid component. In any event, claims 16-23, 41 and 42 are directed to a product. Any properties exhibited by the product are inherent. The future intended use of the product does not provide patentability to the product over the prior art.

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19. Claims 16-21 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/22078. US 6,171,334 B1 (347) is used as an English language equivalent for the purposes of citation.

US '347 discloses a multicomponent kit comprising a first composition for oxidative dyeing of hair and a second reducing composition with a pH of 1.8-6. The reducing composition comprises an acid such as alpha-hydroxycarboxylic acids. See claim 18. See Examples 1.1-1.5 bridging columns 11 and 12 for an oxidative hair dye composition comprising sodium hydroxide, sodium lauryl ether sulfate and ammonia and stripper gel compositions (reducing compositions) comprising ascorbic acid, *inter alia*. US '347 discloses at column 11, lines 64-65 that the oxidative hair dye composition is applied with an artist's brush. For the pH value of the oxidative dye composition preferably from 5 to 9, see column 9, lines 7-8. This either overlaps or encompasses the pH ranges instantly claimed. US '347 discloses at column 9, lines 14-16 that buffers such as alkali carbonates can be added to the compositions. For surfactant/emulsifiers, see column 8, lines 52-57.

Response to Arguments

20. Applicant's arguments filed December 21, 2000 have been fully considered but they are not persuasive.

21. Applicant argues that US '949 is directed to cosmetic masks that are peeled or scraped off whereas the instant invention requires that the composition is not rinsed off of the skin. Firstly, it is noted that the product claims are not limited by a future intended

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use. Therefore, the recitation that the compositions are not rinsed off of the skin in claims 16-23, 41 and 42 does not provide patentability to the claims. With regard to the method claims, as admitted by Applicant, the compositions of US '949 are removed from the skin by means of a scraper or cloth. US '949 does not disclose or require that the compositions be rinsed off of the skin. It is the Examiner's position that US '949 anticipates the instantly claimed inventions.

22. Applicant argues that the instant invention does not employ a "foamable cosmetic mask" as disclosed in Davis. The instant claims do not exclude a foamable composition. Additionally, the compositions of the prior art contain the same components as the instantly claimed invention. Therefore, the prior art compositions and the instantly claimed invention would inherently exhibit the same properties, such as foamability. Inherent properties do not render product or composition claims patentable over the prior art. Applicant has not provided any limitations in the claims that would distinguish over the prior art.

23. Applicant argues superior and unexpected results as evidenced by the statements at page 11, line 20 to page 12, line 5 of the instant specification. Applicant has not provided any comparative data of the instant invention and the prior art in order to determine unexpected results.

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,720,949 (949).

US '949 discloses all of the limitations of the claims as stated in the 35 U.S.C. 102(b) rejection above. It does not explicitly disclose octoxynol-9 as a surfactant. US '949 discloses at column 6, line 18 that octoxynol-7, octoxynol -10 and octoxynol -14 are all suitable surfactants. Octoxynol-9 is a known surfactant. It is within the skill in the art to substitute one known octoxynol surfactant for another, especially when the difference is only one or two ethoxy groups.

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute octoxynol-9 for the octoxynol substances disclosed in US '949 with the reasonable expectation of obtaining the same emulsification effects.

26. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,720,949 (949) in combination with US 4,797,273 (273) and Database REGISTRY on STN for polysorbate-20.

US '949 teaches all the limitations of the claims as stated as stated in the 35 U.S.C. 102(b) rejection above. It does not explicitly disclose polysorbate-20. US '273 teaches that polysorbate-21, which is equivalent to polysorbate-20 as evidenced by the REGISTRY file printout for polysorbate-20 obtained on STN, is a known surfactant for use in skin care compositions (col. 6, lines 14-18).

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '949 using polysorbate-20 as taught by US '273 expecting to obtain an emulsified composition.

27. Claims 33, 38, 41, 42 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,720,949 (949) in combination with US 5,242,433 (433).

US '949 discloses all of the limitations of the claims as stated as stated in the 35 U.S.C. 102(b) rejection above. It does not disclose using a pad as an applicator for the compositions. US '433 discloses a packaging system of applicator pads for topical drug delivery and a method of applying two dermatological agents to the skin sequentially using the applicator pads (title and abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the compositions of US '949 in the packaging system of US '433 expecting to provide a convenient means of dispensing a plurality of substances, overcome the physical and chemical incompatibilities of the substances and allow for sequential application.

28. Claims 16-21, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/22078 using US 6,171,347 B1 (347) as an English language equivalent in combination with US 5,242,433 (433).

US '347 teaches all of the limitations of the claims as stated in the 35 U.S.C. 102(b) rejection above. It does not teach applicator pads. US '433 discloses a packaging system of applicator pads (title and abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the compositions of US '347 in the packaging system of US '433 expecting to provide a convenient means of dispensing a plurality of substances, overcome the physical and chemical incompatibilities of the substances and allow for sequential application.

29. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/22078 (US '347) in combination with US 5,304,370 (370).

US '347 teaches all of the limitations of the claims as stated in the 35 U.S.C. 102(b) rejection above. It does not teach octoxynol-9 or polysorbate-20. US '370 teaches that octoxynol-9 and polysorbate-20 are suitable surfactants for hair care compositions.

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute either octoxynol-9 or polysorbate-20 for the surfactant in US '374 expecting to obtain an emulsified composition.

Response to Arguments

30. Applicant's arguments with respect to claim 22 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

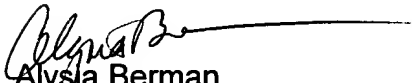
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-


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4638. The examiner can normally be reached on Monday through Friday from 8:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 or 703-305-4556 for regular communications and 703-308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.


Alysia Berman
Patent Examiner
June 01, 2001


DIANA DUDASH
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